

Department of Licensing and Regulatory Affairs
Bureau of Professional Licensing

NOTICE OF PUBLIC HEARING

September 21, 2021

1:00 p.m.

Location: G. Mennen Williams Building Auditorium
525 W. Ottawa Street, Lansing, Michigan

The hearing is held to receive public comments on the following administrative rules:

Pharmacy – General Rules (MOAHR #2020-128 LR)

Authority: MCL 333.16141, MCL 333.16145, MCL 333.16148, MCL 333.16174, MCL 333.16175, MCL 333.16178, MCL 333.16182, MCL 333.16186, MCL 333.16201, MCL 333.16204, MCL 333.16204e, MCL 333.16205, MCL 333.16215, MCL 333.16287, MCL 333.17707, MCL 333.17721, MCL 333.17722, MCL 333.17731, MCL 333.17737, MCL 333.17739, MCL 333.17742a, MCL 333.17742b, MCL 333.17746, MCL 333.17748, MCL 333.17748a, MCL 333.17748b, MCL 333.17748e, MCL 333.17751, MCL 333.17753, MCL 333.17754a, MCL 333.17757, MCL 333.17760, MCL 333.17767, MCL 333.17775, and Executive Reorganization Order Nos. 1991-9, 1996-2, 2003-1, and 2011-4, MCL 338.3501, 445.2001, 445.2011, and 445.2030.

Overview: The proposed revisions to the rules will: require preceptors to report internship hours; require an applicant who has failed the NAPLEX or the MPJE to review the material in a preparation course or with an instructor; clarify that an applicant who has completed the FPGE certification has met the English proficiency requirement; allow an applicant for licensure by endorsement to obtain a license in this state if he or she either holds a license in another state or holds a license in Canada and meets additional requirements; add requirements for relicensure; establish the requirements for a remote pharmacy license; provide a waiver process from the 10 mile requirement for remote pharmacies; require any pharmacy that will provide sterile compounding in this state to submit an onsite physical inspection and report completed no more than 18 months before the application; clarify that a pharmacy that starts or resumes sterile compounding must apply to the Department and submit the required inspection report; require a pharmacy, manufacturer, wholesale distributor, and wholesale distributor-broker that is closing to maintain records; clarify the process for renewal versus relicensure; add the requirements for a facility manager for a manufacturer; adopt the federal exclusions to the definition of wholesale distribution; add the licensure and record keeping requirements for a wholesale distributor-broker; reduce the time from 3 years to 2 years before a prescription may be electronically duplicated; provide the requirements for electronic transmission of prescriptions; provide the process for a waiver from the mandate to electronically transmit a prescription; and clarify that if final product verification is delegated, then both the pharmacist and technician must record their initials.

The rules will take effect immediately upon filing with the Secretary of State, unless specified otherwise in the rules. Comments on the proposed rules may be presented in person at the public hearing. Written comments will also be accepted from date of publication until **5:00 p.m. on September 21, 2021**, at the following address or e-mail address:

Department of Licensing and Regulatory Affairs

Bureau of Professional Licensing– Boards and Committees Section
P.O. Box 30670
Lansing, MI 48909-8170
Attention: Policy Analyst Email: BPL-BoardSupport@michigan.gov

A copy of the proposed rules may be obtained by contacting Board Support at (517) 241-7500 or the email address noted above. Electronic copies also may be obtained at the following link:

Pharmacy – General Rules

<https://ars.apps.lara.state.mi.us/Transaction/RFRTransaction?TransactionID=56>

Individuals attending the meeting are requested to refrain from using heavily scented personal care products, in to enhance accessibility for everyone. People with disabilities requiring additional accommodations (such as materials in alternative format) to participate in the meeting should call (517) 241-7500.